UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/252,691	02/18/99	WEINSTOCK K	107196.135

HM22/0713

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EXAMINER	
PORTNER, V	
ART UNIT	**PAPER NUMBER**
1645	14

DATE MAILED: 07/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/252,691	Weinstock et al
Examiner	**Group Art Unit**
Portner	1641

X Responsive to communication(s) filed on *Feb 18, 1999* .

[ ] This action is **FINAL**.

[ ] Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

X Claim(s) *1-28* is/are pending in the application.

Of the above, claim(s) *14-28* is/are withdrawn from consideration.

[ ] Claim(s) _____ is/are allowed.

X Claim(s) *1-13* is/are rejected.

[ ] Claim(s) _____ is/are objected to.

X Claims *1-28* are subject to restriction or election requirement.

Application Papers

X See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

[ ] The drawing(s) filed on _____ is/are objected to by the Examiner.

[ ] The proposed drawing correction, filed on _____ is [ ] approved [ ] disapproved.

[ ] The specification is objected to by the Examiner.

[ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

[ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

[ ] All [ ] Some* [ ] None of the CERTIFIED copies of the priority documents have been

[ ] received.

[ ] received in Application No. (Series Code/Serial Number) _____ .

[ ] received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

[ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

X Notice of References Cited, PTO-892

X Information Disclosure Statement(s), PTO-1449, Paper No(s). *5/9/21/99,*

[ ] Interview Summary, PTO-413

[ ] Notice of Draftsperson's Patent Drawing Review, PTO-948

[ ] Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claims 1-28 are pending

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. The provisional applications upon which priority is claimed is acknowledged.

Sequence Letter

2. Applicant's Sequence disk has been received and is in compliance.

3. Two sequences were identified by the examiner located at page 88, line 3 that need to be assigned sequence ID NO to place the entire Application is sequence compliance.

Election/Restriction

4. Claims 14-28 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected Groups II-VI. Election was made **without** traverse in Paper No. 8, dated January 24, 2000.

5. Claims 1-13 of Group I, specifically SEQ ID No 7056 a putative polypeptide of 223 amino acids that corresponds to a nucleic acid sequence of 669 nucleic acids is under examination.

Information Disclosure Statement

6. The information disclosure statement filed September 21. 1999 has been considered as to the merits prior to first action.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-13 are rejected for not distintly claiming Applicant's elected invention. The claims recite non-elected inventions. Deletion of the non-elected inventions from the elected claims could obviate this rejection.

Please Note: Rejections and Objections withdrawn will not be addressed at this time. The examiner is reading the word "encodes" to recite open language analogous to the word comprising.

Claim Rejections - 35 U.S.C. § 101

9. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 1-13 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a specific, credible and substantial asserted utility or a well established utility for the elected invention of SEQ ID NO 7056.

The instant specification discloses SEQ ID No 7056 an amino acid sequence and the polynucleotide that encodes the polypeptide. No specific functions are defined for the protei or polypeptide. At page 53, line 7, the sequence are asserted to have putative identification and function. Table 2 defines SEQ ID No 7056 as a hypothetical protein . It is not characterized as having enzymatic, adhesive characteristic, toxin activity or correspondence to any other proteins which are known to be associated with similar types of bacteria. The use of any polypeptide or polypeptide fragment for a vaccine would not be predictable in the art of vaccines. Boslego shows a well characterized Mycobacterium protein which is highly immunogenic but does not induce a protective immune response. Vaccines are not predictable until the composition has been shown by substantive evidence that the polypeptide has the asserted characteristic. Therefore, an asserted utility of a vaccine would not be credible in the vaccine art, especially for a vary small portion of a polypeptide which may or may not have any immunogenic epitopes

contained therein. Without specific teaching of a substantive utility the person of skill in the art would not be able to use the claimed invention for any known purpose, such as diagnostics or vaccines. The claimed polynucleotide is defined by the utility of the polypeptide it defines. As no specific, credible and substantial utility for the recited SEQ ID NO7056 has been disclosed, the claimed invention has no utility, nor has the protein been shown to evidence a well established utility, such as an enzyme, that is useful in the metabolism of a reagent or in the screening of inhibitors to effect the viability of a known pathogen. Credible utility is used herein refers to the reliability of the statement based on the logic and facts that are offered by the instant specification in support for the assertion of utility. If a protein or polypeptide is not defined by specific functional characteristics, where the protein or polypeptide is located in the bacterium, specifically an intracellular protein, membrane surface protein or a secreted protein, the availability of the bacterial protein to induce an immune response in a host would be in question, or could the protein be used as a diagnostic protein. If no information is provided describing where or how the protein is presented or functions, the use of the protein as a specific marker for diagnostic purposes could not be carried out. As proteins are known to be antigenic, the characteristic of being a diagnostic marker for a bacterial infection or disease in not readily apparent merely by a composition being a protein because all proteins are not diagnostic markers for infection and could be a protein which shares cross reactivity with other bacteria. Therefore the protein would not be specific for identifying the bacteria. If the assertion of a characteristic is credible, the claimed invention would also need to evidence specific utility for claimed subject matter. A claim

to a polynucleotide whose use is disclosed simply as a gene probe or chromosome marker would not be considered to be specific in the absence of a disclosure of a specific DNA target. A polynucleotide sequence which would not be cross reactive, but specific for a specific disease or infection would provide support to an invention as having specific utility and would substantiate the claimed DNA as having diagnostic utility for a specific pathogen or disease. With a substantial utility, the invention is defined for a real world use. Utilities which require or constitute carrying out further research to identify or reasonably confirm a real world context of use does not define a substantial utility. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. Circular reasoning to define a utility does not define a substantive utility. For example, when a protein or antigen fragment is used to stimulate the production of antibodies so the antibodies can be used to identify the protein, the use of the protein is not specific or substantial to anything other than a protein that does not correlate with anything other than itself. A person would not readily use a polynucleotide to produce a protein that does not correlate with anything associated with a bacteria because the protein has not been shown to be specific to that bacteria, nor has the protein been shown to have any credible use that is substantially applicable for testing, discovering or associated with conditions that effect the context of its use. The instant specification does not disclose that the polynucleotide or polypeptide that it encodes correlates or has a well established utility known in the art as being

specific, substantial and credible and would be readily apparent or implied by the properties of the material, alone or taken with the knowledge of one skilled in the art.

11. Claims 1-13 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, credible and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

12. Claims 11-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for probes and primers, vectors and hosts cells, the instant specification , does not reasonably provide enablement for gene therapy using the elected SEQ ID NO 7056. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

13. The specification fails to provide an enabling disclosure for the preparation and use of any compositions, including viral vector compositions comprising nucleic acids encoding antigens because it fails to provide adequate guidance regarding how one would have prepared a nucleic acid which when introduced into a host would induce an immune response against the protein encoded by said nucleic acid. In contrast to direct protein immunogens, nucleic acids are required to target appropriate cell types within a host, become transcriptionally

active, appropriately process any encoded proteins and present such proteins to the host in a manner suitable for recognition by the host's immune system. Such a **"gene therapy"** approach to epitope delivery suffers from all the limitations associated with gene therapy technology. However, as of 12/95, the artisan did not accept, in the absence of suitable and particular guidance, that such could have been accomplished without having had to have exercised undue experimentation. See e.g. NIH Report Reference.

Claim Rejections - 35 U.S.C. § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

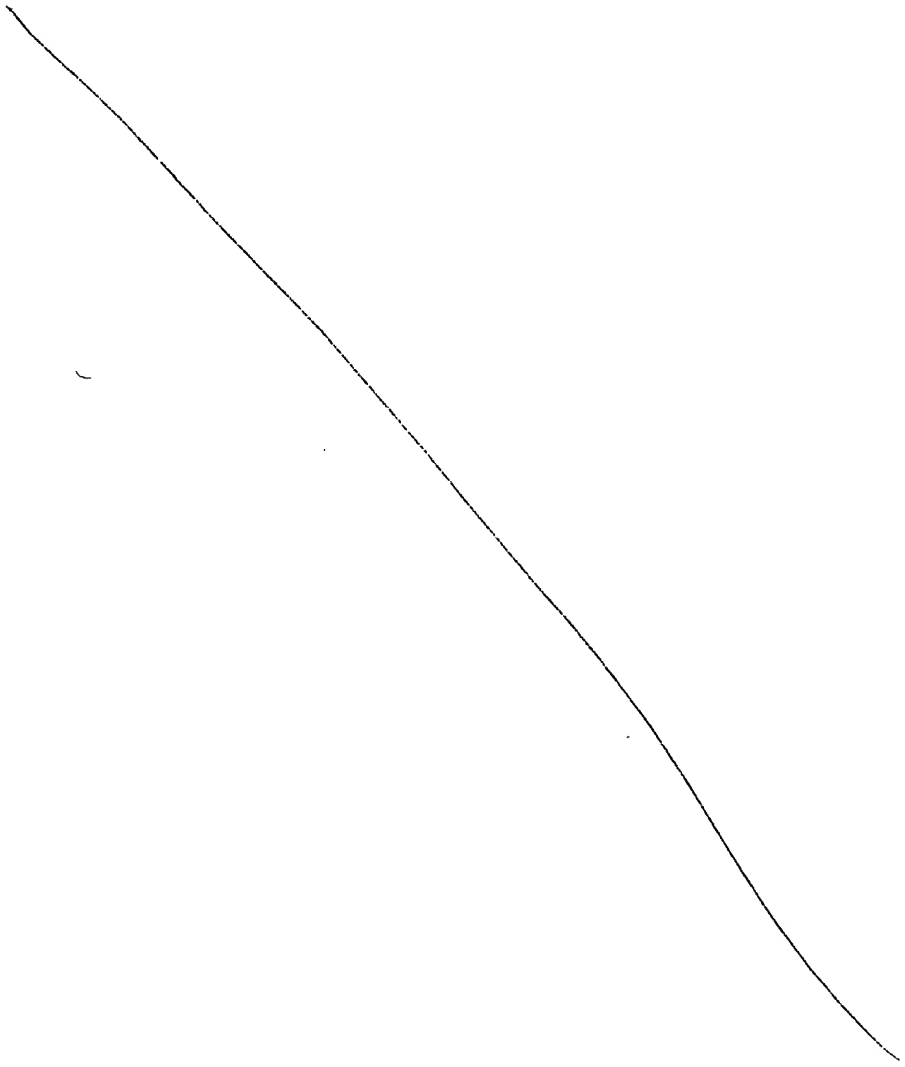
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application

Please Note: The following art rejection is being made of record as the claims recite open language and read on isolated DNA from the entire Enterobacter cloacae chromosome.

15. Claims 1,5,10 are rejected under 35 U.S.C. 102(b) as being anticipated by Haertl, R et al (1993).

Haertl et al disclose fingerprinting of Enterobacter cloacae through first isolating bacterial DNA. Therefore the reference disclose an isolated nucleic acid of Enterobacter cloacae which

would inherently comprise the claimed SEQ ID NO.7056, and fragments of at least 10 nucleic acids, wherein the polynucleotide was DNA obtained from the entire genome of Enterobacter cloacae. Therefore, Haertl anticipates the instantly claimed invention as now claimed.



16. Claims 1,5,10 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsutani. S et al (1991).

Matsutani et al disclose the isolation of total double straned DNA from Enterobacter cloacae. Therefore the reference discloses an isolated nucleic acid of Enterobacter cloacae which would inherently comprise the claimed SEQ ID NO.7056, and fragments of at least 10 nucleic acids, wherein the polynucleotide was obtained from the entire genome of Enterobacter cloacae. Therefore,Matsutani anticipates the instantly claimed invention as now claimed .

17. Claims 1,5,10 are rejected under 35 U.S.C. 102(b) as being anticipated by Lambert-Zechovsky, N et al (1992).

Lambert-Zechovsky, N et al disclose the isolation of total bacterial DNA from Enterobacter cloacae. Therefore the reference discloses an isolated nucleic acid of Enterobacter cloacae which would inherently comprise the claimed SEQ ID NO.7056, and fragments of at least 10 nucleic acids, wherein the polynucleotide was obtained from the entire genome of Enterobacter cloacae. Therefore, Lambert-Zechovsky, N et al anticipates the instantly claimed invention as now claimed .

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner

can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be changing February 7, 1998. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 1641.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp
June 19, 2000

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641